

Pursuant to 37 CFR §1.121(c)(1)(ii), a marked up version of these claims accompanies this amendment.

#### REMARKS

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

The rejection of claims 1, 5, 6 and 7 under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,294,518 to Potter et al. ("Potter") is respectfully traversed.

Potter relates to inhibiting a HIV virus (a retrovirus, i.e. a single stranded RNA virus) and does not disclose viral replication being treated, decreased or, in fact, being caused by a DNA virus. Accordingly, the rejection is improper and should be withdrawn.

The rejection of claims 1, 5, 9, 13 and 17 under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,776,933 to Gordon et al. ("Gordon") is respectfully traversed.

Gordon relates to inhibiting a HIV virus and does not disclose viral replication being treated, decreased or, in fact, being caused by a DNA virus. Accordingly, the rejection is improper and should be withdrawn.

The rejection of claims 1, 5, 9, 13, 17 and 18 under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,410,704 to Roizman et al. ("Roizman") is respectfully traversed.

Roizman relates to the identification, purification and use of a herpes protease. Roizman solely discloses **viral** proteases; Roizman does not, however, disclose decreasing the levels of functional **cellular** protease in cells. Accordingly, the rejection is improper and should be withdrawn.

The rejection of claims 1, 5-9 and 13-17 under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,607,831 to Henkart et al. ("Henkart") is respectfully traversed.

Henkart relates to methods of inhibiting cell death

and deterioration by retroviral infection. Henkart does not disclose viral replication being treated, decreased or, in fact, being caused by a DNA virus. Accordingly, the rejection is improper and should be withdrawn.

The rejection of claims 1, 5-9 and 13-17 under 35 U.S.C. § 112 (first paragraph) for lack of enablement is respectfully traversed.

In order for claims to be enabled, the specification, when filed, must contain sufficient information as to enable one skilled in the art to make and use the claimed invention. (Manual of Patent Examining Procedure ("MPEP") 2164.01). As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, the enablement requirement is satisfied. (In re Fisher, 427 F.2d. 833, 839, 166 USPQ 18, 24 (CCPA 1970); MPEP 2164.01(b)). In determining whether a patent application is in compliance with the enablement requirement, the PTO will consider whether one of ordinary skill in the art could practice the invention without undue experimentation. In re Wands, 858 F.2d. 731, 8 USPQ2d 1400 (Fed. Cir. 1988)). Some experimentation may be required, as long as the experimentation is not undue.

The claims of the application set forth methods which decrease levels of functional cellular protease to decrease DNA viral replication. These claims are fully enabled. In particular, one of ordinary skill in the art could contact cells with a DNA virus, contact the infected cells with the inhibitor and determine whether the replication of the virus was inhibited. These steps could be achieved by one of ordinary skill in the art without undue experimentation. As set out in the present application, cells are infected with a DNA virus (specification, page 22, line 25- page 23, line 5). Treating viral infected cells with

inhibitors of cellular proteases and the measurement of the resultant viral infection is known in the art and described in the cited prior art. In particular, one of ordinary skill in the art could readily ascertain whether viral replication was decreased, the unpredictability of the particular mechanism of replication notwithstanding. Lastly, measurement of the level (or activity) of a cellular protease, such as calpain, is described (specification, page 25, lines 7 - 33) and known in the art (See Potter, column 14, example 6). Thus, one of ordinary skill in the art could practice the present invention without undue experimentation with the information known in the art and contained in the specification. Further, as discussed by the PTO (see outstanding office action page 6), prior art is available which teaches one of ordinary skill in the art how to infect cells with a virus and test to determine if viral replication is decreased. Accordingly, the rejection is improper and should be withdrawn.

Enclosed are ten sheets of formal drawings.

In view of the foregoing, applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

April 23, 2003  
Date

Karla M. Weyand  
Karla M. Weyand  
Registration No. 40,223

Braman & Rogalskyj, LLP  
P.O. Box 352  
Canandaigua, New York 14424-0352  
Tel: 716-626-5380  
Fax: 716-626-5384

I:\026\00041\B4

<b>Certificate of Mailing - 37 CFR 1.8 (a)</b>	
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mailing an envelope addressed to: Assistant Commissioner of Patents and Trademarks, Washington, D.C. 20231, on the date below.	
4/23/03 Date	<u>Karla M. Weyand</u> Karla M. Weyand

**Appendix: Marked up Claims**

1. (Amended) A method of decreasing viral replication in cells, the method comprising decreasing levels of functional cellular protease in the cells by exposing the cells to an inhibitor of the functional cellular protease, wherein the viral replication is caused by a DNA virus.

9. (Amended) A method of treating [or preventing] a viral infection in a subject, the method comprising administering to the subject an amount of a compound effective to decrease levels of functional cellular protease in cells of the subject wherein the viral infection is caused by a DNA virus and the compound is an inhibitor of the functional cellular protease.

SOH CENTER 10015001

W A F 1001

1001-1001